# Clinical Feasibility and Evaluation Study of POINT-GUARD Embolic Protection Device During TAVR (GUARDIAN)

NCT06962371

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| **Status** | RECRUITING |
| **Phase** | Not Applicable |
| **Sponsor** | Transverse Medical, Inc. |
| **Enrollment** | 30 participants |

## Key Eligibility Criteria

### Inclusion (4)

- The patient is e18 years of age;
- The patient meets indications for Transcatheter Aortic Valve Replacement (TAVR);
- The patient is willing to comply with protocol-specified follow-up evaluations;
- The patient has been informed of the nature of the study, agrees to its provisions, and has provided written informed consent, approved by the appropriate Institutional Review Board or Ethics Committee.

### Exclusion (17)

- TAVR conducted via other than transfemoral access (subclavian, axillar, transapical, transaortic, carotid or transcaval).
- Anatomy that precludes safe delivery and retrieval of the investigational device.
- Current or planned treatment with any investigational drug or investigational device during the study enrollment or follow-up period.
- Cardiovascular surgical or interventional procedure 10 days prior or planned during the TAVR procedure or during the 30-day study follow-up.
- Patients with uncontrolled bleeding disorders.

... and 12 more (see full listing online)

## Locations (1 total)

Victorian Heart Hospital, Clayton, Victoria, Australia